



Procter&Gamble

The Procter & Gamble Company
Health Care Research Center
8700 Mason-Montgomery Road, Mason, Ohio, 45040

April 29, 2005

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

MAY - 4 2005

Re: New Dietary Ingredient Notification for *Bifidobacterium infantis* 35624

Dear Sir/Madam,


In accordance with FDA regulations at 21 CFR §190.6, The Procter & Gamble Company (P&G) is hereby issuing this 75-day pre-market notification of its intent to market *Bifidobacterium infantis* Strain 35624 (trade name "Bifantis") as a new dietary ingredient. The original notification is enclosed along with two copies.

The product will be marketed in encapsulated form at a daily dose of up to 1×10^{10} colony forming units. The strain will be manufactured by The Christian Hansen Company for P&G. Christian Hansen considers its manufacturing and facility information to be trade secret in accordance with 21 CFR §20.61 and will submit confidential manufacturing process and facility information directly to FDA under separate cover.

The product will not be marketed for a period of at least 75 days succeeding this notification and acceptance by the Agency. Should you have any questions regarding this notification, feel free to call me at 513-622-1599, or e-mail to johnson.bn@pg.com. We will respond promptly to any questions you might have.

Sincerely,

THE PROCTER & GAMBLE COMPANY


Bradley N. Johnson, Ph.D.

US Regulatory Affairs, Personal Health Care

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